UNITED STATES DEPARTMENT OF COMMERCE
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/142,524 | 01/04/99 | SONE T | SPO-103 |

HM12/0630

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| EXAMINER | |
|---|---|
| DIBRINO,M | |
| **ART UNIT** | **PAPER NUMBER** |
| 1644 | 6 |

**DATE MAILED:** 06/30/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/142,524 | Sone et al |
| **Examiner** | **Group Art Unit** |
| Marianne DiBrino | 1644 |

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *1-9* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-9* are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to Comply with Sequence Rules

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

**DETAILED ACTION**

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant is required to fulfill these requirements by defining the SEQ ID NOS in both the specification and claims and by providing a CRF of the Sequence Listing and a statement that the content of the CRF and paper copies are the same and where applicable, include no new matter.

2. Applicant's submission of the instant application as a 371 is acknowledged, however the claim 1 of the instant application does not provide a technical feature that is distinguished over the prior art, as evidenced by Rogers et al (Molecular Immunology, Vol. 31 (13) pp 955-966, 1994, entire document) and by WO 94/01560 (20 January 1994, entire document, especially page 26, lines 25-31, page 28, lines 19-21 and pages 35, 36, lines 31-32 and lines 1-5, respectively). Rogers et al teach a peptide-based immmunotherapeutic agent comprising a linear multi-epitope peptide with different T cell epitope regions joined to each other and which do not substantially react with allergic human IgE. The WO 94/01560 document teaches linear polypeptides comprising at least two different T cell epitope regions joined to each other which do not substantially react with allergic human IgE. These latter polypeptides have epitope regions with positivity indices of at least about 100. The WO document also teaches that peptides are selected based upon various factors including the frequency of the T cell response to the peptide in a population of individuals sensitive to the allergens and the strength of the T cell response to the peptide. It also teaches pharmaceutical compositions containing these polypeptides which comprise a sufficient percentage of the T cell epitopes such that at least about 60% of the T cell reactivity of the allergens are included in the composition. It would have been obvious to choose the epitope regions of Rogers based upon the teachings of the WO document, and it would be obvious to make a pharmaceutical composition which reacts with T lymphocytes of not less than 70% of the population senstive to the allergen(s).

Therefore, the instant invention lacks Unity of Invention.

3. Applicant is required under 35 U.S.C. 121 (1) to elect a single disclosed species (**a specific peptide-based immunotherapeutic agent**) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

For example, if applicant elects the immunotherapeutic agent of claim 3, applicant is further required to elect a specific multi-epitope peptide containing particular peptides disclosed in the instant application from cedar pollen allergens Cry j 1 and Cry j 2, i.e., a specific SEQ ID NO, and to identify the HLA class II molecule to which the multi-epitope peptide is restricted.

For instance, applicant might elect one of SEQ ID NO: 1, 2 ***or*** 3.

For example, if applicant elects the immunotherapeutic agent of claim 8, applicant is further required to elect a specific multi-epitope peptide containing an amino acid sequence disclosed in the instant application from Cry j 1 and *hinoki* pollen allergen Cha o 1. For instance, applicant might elect either SEQ ID NO: 4 ***or*** 5.

4. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48 (b) and by the fee required under 37 C.F.R. 1.17 (h).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Marianne DiBrino, Ph.D.
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Group 1640
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June 25, 1999